



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,232	01/14/2002	Krzysztof Chwalisz	SCH 1537 D2	7422
23599	7590	11/18/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.			MITCHELL, GREGORY W	
2200 CLARENDON BLVD.			ART UNIT	
SUITE 1400			PAPER NUMBER	
ARLINGTON, VA 22201			1617	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/043,232

Applicant(s)

CHWALISZ ET AL.

Examiner

Gregory W. Mitchell

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-14, 33-35 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14, 33-35 and 48-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action is in response to the Remarks and Amendments filed August 22, 2005. Claim 53 has been amended. Claims 12-14, 33-35 and 48-54 are pending and are examined herein.

Applicant's amendments are sufficient to overcome the 35 USC 112(2) rejection of claims 53 and 54. Furthermore, Applicant's amendments are sufficient to overcome the objection to claim 53.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***35 USC § 103 Rejection Maintained***

Claims 12-13, 33-34 and 48-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Deutsch et al. (USPN 4,447,424) for the reasons set forth in the Office Action dated April 22, 2005.

Claims 12, 14, 33, 35 and 48-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Jones et al. (USPN 5462949) for the reasons set forth in the Office Action dated April 22, 2005.

Claims 12, 33, 48-54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Chwalisz et al. (USPN 5439913) for the reasons set forth in the Office Action dated April 22, 2005.

Applicant argues, "not one of these references teaches or suggests that nitric oxide synthase inhibitors can be combined with antiprogestins in synergistically effective

Art Unit: 1617

amounts, which is required by the methods claimed.” This argument is not persuasive. It is noted that the prior art need not teach that the amount used is actually synergistic, but that it must simply be in an amount that *is* synergistic to meet the pending claims. Furthermore, a mere argument that the combination of nitric oxide synthase inhibitors with antiprogestins is synergistic is insufficient to rebut a *prima facie* case of obviousness. A showing of unexpected results is required.

Applicant continues by arguing, “Applicant previously provided a declaration with extensive amounts of data on studies involving three pair of synergistically effective amounts of nitric oxide synthase inhibitor in combination with an antiprogestin.” This argument is not persuasive because a showing that three combinations exhibit synergistic results is insufficient to illustrate that any nitric oxide synthase inhibitors in combination with any antiprogestin will have synergistic or unexpected results. Thus, Applicant’s arguments that “Whatever legitimacy thus may be to the underlying presumptions per se, such must fall in the face of actual data demonstrating the unexpected synergism of the combinations in the claimed methods contrary to the conclusions examiner draws based on these presumptions” because, quite simply, the showing of unexpected results *are not commensurate with the scope of the claims*.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER